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ALLIANCES IN MEXICO
AND SRI LANKA

February 12, 2020

VIA ECF

The Honorable Joel Schneider
United States Magistrate Judge
District of New Jersey
Mitchell H. Cohen Building & U.S.
Courthouse
4th & Cooper Streets, Courtroom 3C
Camden, NJ 08101

Re: In re Valsartan, Losartan, and Irbesartan Products Liability Litigation
Case No. 1:19-md-02875-RBK-JS

Dear Judge Schneider:

This letter is to provide Defendants' positions with respect to the topics on the agenda for the Case Management Conference with the Court on February 13.

1. Downstream Defendant Discovery

The downstream Defendants continue to meet and confer with Plaintiffs regarding discovery targeted toward these tiers, mindful of the Court's assurances that any such discovery should be tailored in scope. Counsel for the retailers and wholesale/distributor Defendants sent a list of common questions and concerns regarding plaintiffs' most recent draft Rule 34 discovery and draft DFS. Plaintiffs have provided responses to those questions and, on Wednesday, February

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12, representatives for Plaintiffs, the retailer Defendants and the wholesaler/distributor Defendants then conferred via phone to discuss Plaintiffs' responses. The parties continue to meet and confer on these issues, with the downstream defendants to send redlines to Plaintiffs to further guide their negotiations. The parties anticipate further cooperation and meet and confer efforts, and will seek Court guidance to the extent necessary in subsequent correspondence to the Court.

2. Related Actions Pending Outside the MDL

During the January 28, 2020 Case Management Conference, the Court requested an update on the status of related actions pending outside of this MDL. The chart attached as Exhibit A lists related actions pending in state courts, as well as federal actions in which one or more parties is opposing transfer to the MDL.

3. Improperly Filed Short Form Complaints

On January 14, 2020, Defendants filed a list of Plaintiffs who had (1) failed to serve their Short Form Complaints ("SFCs") through MDL Centrality; (2) served their SFCs through MDL Centrality, but in a way that did not allow the platform's data reporting tools to be used; or (3) entirely failed to file a SFC by the applicable deadline in Case Management Order No. 13 (Dkt. 187) (requiring all then-currently filed personal injury cases to file a SFC within 30 days). *See* Dkt. 338-4, Exhibit D (providing list of delinquent Plaintiffs). On January 16, 2020, the Court ordered that those Plaintiffs properly file and serve their SFCs by January 27. *See* Dkt. 342 at 1-2. As of the date of this filing, the Plaintiffs listed on attached Exhibit B have not complied with the Court's order. Accordingly, Defendants request that the Court issue Orders to Show Cause directed toward these Plaintiffs. *See* Jan. 16 Order, Dkt. 342 at 1-2 (stating that Court would direct Orders to Show Cause toward plaintiffs who failed to meet January 27 deadline).

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4. Overidentification of Defendants in Short Form Complaints

Defendants continue to review and assess the Short Form Complaints (“SFC”) filed by Plaintiffs. One pressing issue which has arisen in the course of this review and analysis is the frequency with which Plaintiffs are filing SFCs identifying each and every Defendant at various levels of the supply chain. Specifically, many Plaintiffs have filed SFCs which identify each and every Defendant above the retailer/pharmacy level. Currently, Defendants have reviewed seven (7) cases where each and every Defendant listed on the SFC is identified, and twenty-six (26) additional cases where all Defendants above the retailer/pharmacy level are identified. *See Exhibit C.*

This overidentification is problematic and inappropriate. Overidentification impacts reporting and insurance requirements for the improperly-named Defendants and risks requiring otherwise peripheral Defendants to stay active in the litigation. This manner of filing SFCs also complicates the PFS review process, as Defendants are unable to rely on Plaintiff’s SFC and must instead review the PFS for each of these Plaintiffs to determine if a given party is actually implicated by the Plaintiff’s claims. As the Court noted in the context of addressing the issue of peripheral Defendants being dragged into Court by Plaintiffs checking every box on the SFC, there are obvious “Rule 11 concerns” that surround this method of filing cases. (CMC 11 Tr. at 55:20-56:5). Defendants submit this holds true where each and every Defendant is identified and in cases where the only specificity Plaintiffs attempt is with respect to retailers/pharmacies where the product was purchased. The FDA maintains a freely accessible, searchable database with information on recalled Valsartan, Losartan, and Irbesartan products. *See* “FDA Updates and Press Announcements on Angiotensin II Receptor Blocker (ARB) Recalls (Valsartan, Losartan, and

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Irbesartan),” *available at* <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan> (last accessed Feb. 12, 2020). Moreover, to the extent a Plaintiff cannot, after reasonable inquiry, identify an appropriate Defendant, the Short Form Complaint was drafted with a “John Doe” at each level to accommodate Plaintiffs who truly cannot determine Defendants at a given level of the supply chain.

As the Court has stated on multiple occasions, Plaintiffs must do their due diligence before filing a Short Form Complaint in this MDL. When the Court was finalizing the SFC, Plaintiffs suggested that some attorneys might “check all the boxes” for all Defendants and figure out the suppliers of their clients’ valsartan later. *See* 7/10/19 Tr. at 21:12–19. In response, the Court stated that such behavior would “be subject to Rule 11.” *Id.* at 22:12. The Court warned that there will “be consequences if plaintiffs...don’t do due diligence and sue defendants who they have no good faith basis to sue.” *Id.* at 22:16–18; *see also id.* at 23:4–9 (stating that “closer scrutiny should be paid” in an MDL to weed out bad faith claims and that “a plaintiff’s attorney has to do due diligence before they check a box”).

Plaintiffs seeking to avail themselves of this Court’s jurisdiction must be required to put forth appropriate effort to determine the parties rightly involved in their respective cases. This requirement is particularly meaningful given the fact that Defendants are not able to pursue dismissal from these cases via motion at this time. Accordingly, the Defendants request that the Court order the Plaintiffs in cases listed on Exhibit C to amend their Short Form Complaints to appropriately identify Defendants in accordance with Federal Rule of Civil Procedure 11, and that

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to the extent such amendment does not take place by whatever deadline the Court imposes, Defendants may be permitted to seek sanctions.

5. Plaintiff Fact Sheets

Defendants continue to review Plaintiff Fact Sheets and serve notices identifying core deficiencies. Per CMO 16, Defendants will list disputes relating to the Plaintiff Fact Sheets on the agenda for in-person case management conferences, to the extent such disputes remain unresolved following the service of the deficiency notice and any response received within 2 weeks of that notice.

In the course of reviewing the Plaintiff Fact Sheets, Defendants have identified two overarching issues for which they seek the Court's guidance outside of the show cause process. These issues are described more fully below.

(a) Plaintiffs Filing Both Personal Injury and Medical Monitoring Fact Sheets

Certain Plaintiffs have filed both Personal Injury and Medical Monitoring Fact Sheets. These are personal injury Plaintiffs who have filed Short Form Complaints in the personal injury proceeding, and who are not named plaintiff in the medical monitoring putative class action. Defendants seek clarification from the Court that those who have filed a Short Form Personal Injury Complaint should be submitting only Personal Injury Plaintiff Fact Sheets.

(b) Collateral Resource Rule Objections

Several personal injury plaintiffs have objected to providing certain information requested in the Personal Injury Plaintiff Fact Sheet, invoking the collateral source rule. Specifically, these plaintiffs have relied on this rule to avoid supplying information concerning medical insurance

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carriers, including carrier names, dates of coverage, and policy numbers, insurance record authorizations, and other information.

Defendants maintain that the Plaintiffs are required to provide all information requested in the Plaintiff Fact Sheets, which were agreed between the Parties and approved by Court Order. *See* Case Management Order No. 16 (Dkt. 249). Plaintiffs agreed to provide this information in agreeing to the fact sheets, and the time for objections to the nature of the information sought has passed.

Additionally, Defendants note that the collateral resource rule is a rule pertaining to *admissibility* of evidence. *See, e.g., Ochoa v. Mercer Transportation Co.*, No. 5:17-CV-1005-OLG, 2018 WL 6220155, at *1 (W.D. Tex. June 8, 2018) (“The collateral source rule, as Plaintiff notes, is a rule of both evidence and damages, but it is not a rule of discovery[.]”). An *admissibility* doctrine is not a proper basis to withhold information sought in discovery. *Id.* As the Court is aware, the Federal Rules provide that parties “may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case,” and that information “need not be admissible in evidence to be discoverable.” Fed. R. Civ. P. 26(b)(1).

Defendants have identified any failure to provide the requested insurance information as a deficiency in a notice to Plaintiffs, but in the interest of avoiding future disputes seek clarification from the Court that each Plaintiff is required to provide all available information requested in the applicable Plaintiff Fact Sheet, and specifically that the Court will deem withholding of information relating to a Plaintiffs’ health insurance policies to constitute a failure to submit a substantially complete Fact Sheet.

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6. Direct Filing Order

Consistent with the Court's January 30, 2020 Order (Dkt. 360), the Defendants who have objected to and do not stipulate to the direct filing of complaints against them in this multidistrict litigation (the "Objecting Defendants") have repeatedly attempted to engage with Plaintiffs regarding the form of an amended Direct Filing Order that would effectuate the Court's directive that direct filing should proceed over the Objecting Defendants' objections. At the request of Plaintiffs' counsel, Objecting Defendants sent Plaintiffs a revised alternate Superseding Direct Filing Order on Sunday, February 9 modeled after the "alternate" order previously discussed with plaintiffs and the Court.

During a telephonic meet and confer the evening of February 12, Plaintiffs' counsel suggested that Plaintiffs would soon send a redline with proposed changes to the draft alternate order for the Objecting Defendants to review. Objecting Defendants look forward to reviewing and conferring with Plaintiffs as necessary to finalize an order by February 18 that appropriately acknowledges the Objecting Defendants' standing objections to direct filing and to the entry of a direct filing order, as well as expressly preserves all Defendants' rights, defenses and arguments as agreed by all parties during January's case management conferences and as contemplated by the Court's January 30 Order.

7. Substituting Defendants in Master Economic Complaint

Plaintiffs seek to "substitute" for "John Does" listed in the plaintiffs' consolidated amended economic loss class action complaint in Case No. 19-md-2875, Dkt. No. 121, Cardinal Health, McKesson Corporation, AmerisourceBergen Corporation, Albertsons Companies LLC, Humana Pharmacy Inc., OptumRx, and Optum, Inc. (collectively the "Proposed Substitute

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Defendants”). Proposed Substitute Defendants are not agreeable to Plaintiffs’ proposed stipulation to “Amend Caption and Parties in Consolidated Amended Economic Loss Class Action Complaint.” Plaintiffs are required to abide by Rule 15 if they seek to add parties in the economic loss class action matter. Plaintiffs’ proposed stipulation is not a proper vehicle by which to amend a complaint under the federal rules to add parties. There is no procedure in the Federal Rules to “amend caption” to add parties or to “substitute parties” for previously identified “John Doe” defendants. Rather, the proper procedure for amending a complaint to add parties is Federal Rule of Civil Procedure 15, which requires Plaintiffs to amend only with either (1) opposing party’s written consent or (2) leave of court. In either scenario, Plaintiffs seeking to amend a complaint are required to prepare and propose an actual amended complaint that includes a caption with a listing of the defendants who are named as parties to the case in the body of the complaint (See F.R.C.P. 10) and that includes the factual contentions that plaintiffs assert provide the bases for their claims against those parties to be added. Plaintiffs’ proposed stipulation to “amend caption and parties” does neither. Indeed, there is no caption on Plaintiffs’ previously filed Consolidated Amended Economic Loss Class Action Complaint previously filed, and Plaintiffs’ proposed stipulation merely seeks to adopt allegations against Proposed Substitute Defendants from other complaints (to the extent they exist) rather than asserting legal and factual contentions to support claims against Proposed Substitute Defendants in the economic loss class action matter.

This is more than form over function. One purpose of these rules is to put Defendants on notice of the claims asserted against them and the factual allegations that support such claims. This is all the more important here because the defendants are not permitted to challenge the sufficiency of the pleadings by motion practice at this time. The Proposed Substitute Defendants have asked

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that Plaintiffs provide a proposed amended complaint for their review but Plaintiffs did not respond. Once Plaintiffs prepare and propose an actual amended complaint, the Proposed Substitute Defendants should then have an opportunity to review the complaint and to determine their position on the proposed amendment.

8. Default Against Aurobindo Pharma Pursuant to Article 15 of the Hague Convention

Consistent with Plaintiffs' February 6 Letter (Dkt. 362), the Defense Executive Committee is unaware of Defendant Aurobindo Pharma having been served in this litigation.

9. Entry of Hetero Drugs and Hetero Labs

Eric Abraham of Hill Wallack LLP has entered appearances on behalf of Hetero Labs Ltd and Hetero Drugs Ltd. and will be asking the Court to direct the Clerk of the Court to add Hetero Drugs Ltd to allow electronic filing on its behalf. Counsel for Hetero has met and conferred with Counsel for Plaintiff to create a plan for Hetero Labs Ltd and Hetero Drugs Ltd to commence full participation in discovery expeditiously, and in compliance with the "Core" Discovery Order (Dkt. 88) and subsequent Order (Dkt. 328) without duplicating the discovery provided to date and yet to be provided by Hetero USA. Counsel for both parties also conferred with respect to the document designated "CONFIDENTIAL" by Hetero USA and to which designation Plaintiffs object. Counsel will further meet and confer pursuant to the Court's directive.

10. Identities of All Third Parties and/or Consultants with Authority to Communicate with the FDA on Behalf of Defendants

Defendants are willing to meet and confer with Plaintiffs regarding information pertaining to third parties and consultants with authority to communicate with the FDA on behalf of Defendants.

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Respectfully submitted,

/s/ Seth A. Goldberg

Seth A. Goldberg

cc: Adam Slater, Esq. *(via email, for distribution to Plaintiffs' Counsel)*
Jessica Priselac, Esq. *(via email, for distribution to Defendants' Counsel)*
Sarah Johnston, Esq. *(via email)*
Lori G. Cohen, Esq. *(via email)*
Clem C. Trischler, Esq. *(via email)*

EXHIBIT A

ACTIONS PENDING OUTSIDE OF THE MDL

Caption	Court	Civ. No.	Judge	Drug
<i>Runo v. Princeton Pharmaceutical Inc.</i>	New Jersey Superior Court, Middlesex County	MID-L-000856-19	Honorable Michael V. Cresitello, Jr.	Valsartan
<i>Orlowsky v. Solco Healthcare U.S., LLC</i>	New Jersey Superior Court, Middlesex County	MID-L-0002554-19	Honorable J.R. Corman	Valsartan
<i>Robertson v. Princeton Pharmaceutical Inc.</i>	New Jersey Superior Court, Middlesex County	MID-L-004228-19	Honorable Patrick Bradshaw	Valsartan
<i>Shanov v. Walgreens Co.</i>	Illinois Circuit Court, Cook County	2018-CG-15272	Honorable Eve Reilly	Valsartan
<i>Estate of George Graham v. Zhejiang Huahai Pharmaceutical Co., Ltd.</i>	New Jersey Superior Court, Middlesex County	MID-L-005191-19	Honorable Thomas D. McCloskey	Valsartan
<i>Stewart v. Princeton Pharmaceutical Inc.</i>	NY State Supreme Court, Bronx County	20540/2020E		Valsartan
<i>Skadas v. Torrent Pharma, Inc.</i>	Illinois Circuit Court, Cook County	2019-L-006840	Honorable Brendan O'Brien	Losartan
<i>Steele v. Zhejiang Huahai Pharmaceutical Co., Ltd.</i>	S.D.N.Y.	1:19-cv-4106	Honorable John G. Koeltl	Losartan
<i>Bokhari v. Torrent Pharmaceuticals Ltd.</i>	N.D. Cal.	3:19-cv-8045	Honorable Jeffrey S. White	Losartan
<i>Garrison v. Camber Pharmaceuticals</i>	E.D. Mich.	5:19-cv-12536	Honorable Judith E. Levy	Losartan

EXHIBIT B

Improper/“Improviently” Filed Short Form Complaints

A. No SFC filed/SFC not served correctly via MDL Centrality:

1. BREAUX, CHRISTOPHER – 19-19151
2. HEWITT, ESTATE OF JUDY – 20-00335
3. PATTON, BEVERLY – 19-17609
4. WALTERS, MALCOLM JAMES – 20-00048
5. ZEHR, SARAH – 19-12935
6. TOWNSEND, JAMES – 19-18407

B. Untimely Filed SFC:

1. FOUGERE, THERESE – 19-17597
2. PITTMAN, CHARLESTON - 19-15638

EXHIBIT C

Overidentification of Defendants in Short Form Complaint (“SFC”)

A. Cases where every Defendant has been identified on the SFC:

1. BELL, SANDY - 19-19171
2. BELL, RICKY - 19-19135
3. HEBERT, BETTY – 19-14647
4. GUITON, SUSAN – 19-07145
5. STEVENS, JOYCELYN - 19-02875
6. TOWNSEND, JAMES - 19-18407
7. WISEMAN, KEN - 19-15548

B. Cases where all defendants are identified OTHER THAN Retailers (no retailers identified):

1. COLE, BOBBY - 19-14948
2. DAVIDSON, CHESTER - 19-14952
3. HOLCOMB, LUCY - 19-15022
4. JUSTICE, TONY - 19-15025

C. Cases where all defendants are identified OTHER THAN Retailers (some retailers identified):

1. BAUER, DANIEL - 19-14865
 - Wal-Mart Inc.
2. BAYS, GLENN - 19-14869
 - Rite Aide Corp.
3. BUCKLEY, VIRGIE - 19-14884
 - OptumRX
 - Optum, Inc.
 - United Health Group
4. BURNS, ALBERTA - 19-14886
 - Wal-Mart Inc.
5. CLOYD, SHERRI - 19-14906
 - The Kroger Co.
6. CORNETT, ELIZABETH - 19-14950
 - Wal-Mart Inc.
7. DEBORD, LISA - 19-14960

- The Kroger Co.
- 8. DURBIN, JOE - 19-15183
 - CVS Health
- 9. ERNEST, ALAN - 19-14974
 - Rite Aide Corp.
- 10. HALSEY, TALMADGE - 19-14995
 - Rite Aid Corp.
- 11. HAYES, CLAYBORNE - 19-15021
 - Cigna Corporation
 - Express Scripts Holding Company
 - Express Scripts, Inc.
 - Wal-Mart, Inc.
- 12. ESTATE OF JUDY HEWITT – 20-00335
 - Cigna Corporation
 - CVS Health
 - Express Scripts Holding Company
 - Express Scripts, Inc.
 - OptumRx
 - Optum, Inc.
 - UnitedHealth Group
 - Walgreens Boots Alliance
- 13. HOWARD, PAUL - 19-15024
 - CVS Health
- 14. LEE, ALBERT - 19-15027
 - CVS Health
- 15. LOOSE, DAVID – 19-21327
 - Cigna Corporation
 - Express Scripts Holding Company
 - Express Scripts, Inc.
 - OptumRx
 - Optum, Inc.
 - UnitedHealth Group
 - Walgreens Boots Alliance
- 16. LOVE, WILLIAM - 19-15030
 - Rite Aide Corp
 - Walgreens Boots Alliance
- 17. MULLINS, JAMES - 19-15043
 - Rite Aide Corp
 - Walgreens Boots Alliance
- 18. NEEDY, LENNY - 19-15051
 - Rite Aide Corp
 - Walgreens Boots Alliance

19. O'DANIEL, ROBYN (MARION) - 19-15087

- The Kroger Co.

20. PITTMAN, CHARLESTON - 19-15638

- CVS Health
- Rite Aid Corp.
- Walgreens Boots Alliance
- Wal-Mart, Inc.

21. REBER, DENNIS - 19-15101

- CVS Health

22. WILKERSON, DARREN - 19- 15140

- CVS Health
- The Kroger Co.